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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/663,889      | 09/18/2000  | Gary J. Nabel        | 8642/91             | 6450             |

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BRINKS HOFER GILSON & LIONE  
P.O. BOX 10395  
CHICAGO, IL 60611

EXAMINER

PARAS JR, PETER

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1632

DATE MAILED: 03/11/2003

15

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/663,889

Applicant(s)

NABEL ET AL.

Examiner

Peter Paras, Jr.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 17 December 2002.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 17-54 is/are pending in the application.
- 4a) Of the above claim(s) 37-54 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 17-36 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All   b) ☐ Some \*   c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

Applicant's amendment received on 12/17/02 has been entered. Claims 21 and 32 have been amended. Claims 1 and 17-54 are pending. Claims 17-36 are under current consideration.

### ***Election/Restrictions***

This application contains claims, 1 and 37-54, drawn to an invention nonelected in Paper No. 13. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

### ***Priority***

Applicant's arguments filed on 12/17/02 have been fully considered but are not found persuasive. Applicants have argued that material may be incorporated by reference into a patent application. Applicants further argue that the instant application incorporates by reference the teachings of U.S. Patent No. 5,328,470, which discloses methods and kits for the site-specific delivery of various compositions (including an expression vector and a catheter). In light of the incorporation by reference of the teachings of the '470 patent Applicants submit that the instant specification supports the claim limitations directed to a kit comprising a catheter and a nucleic acid comprising a gene encoding p21. See pages 2-4 of the amendment.

In response, the Examiner maintains that Applicant's claim of priority to Application Nos. 08/533,942, 09/031,572, and 09/426,325, now US Patent Nos 5,863,904, 6,057,300, and 6,218,372 respectively, stands denied for the reasons of

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record advanced on page 2 of the Office action mailed on 9/12/02. It is further maintained that the claim of priority is denied because the parent applications fail to fulfill the requirement of 35 U.S.C. 120 by not meeting the requirements of the first paragraph of 35 U.S.C. 112, particularly written description and new matter, necessary to support the claims of the instant application. In particular, the following claim limitations have not been described in the instant specification: a kit comprising a catheter and a nucleic acid comprising a gene encoding p21. Applicant's arguments regarding incorporation by reference of the '470 patent for support of the "kit" claim limitations are not found persuasive. The reference to the '470 patent in the instant specification (see page 10), does not even recite the term "kit" and would appear to generally support administration by direct injection of an expression to a tumor.

Reference to the '470 patent appears to be general as the relevant columns and line numbers that would support the instant claim limitations directed to a kit are not recited in the instant specification. Mere reference to another application, patent, or publication is not an incorporation of anything therein into the application containing such reference for the purpose of the disclosure required by 35 U.S.C. 112, first paragraph. *In re de Seversky*, 474 F.2d 671, 177 USPQ 144 (CCPA 1973). See MPEP § 201.06(c) and MPEP § 608.01(p). Moreover, the instant application has not claimed priority to the application that issued as the '470 patent. Applicants are reminded that material needed to accord an application a filing date may not be incorporated by reference. Therefore, if a continuation or divisional application as originally filed incorporates by reference material omitted from the application papers, which is needed to accord the

application a filing date, the application will not be entitled to a filing date. See MPEP § 201.06(c).

Accordingly, in light of the above, the priority claim of the instant application stands denied for the reasons of record.

### ***Oath/Declaration***

Applicants submit that as a result of the incorporation by reference of the '470 patent and for the arguments presented with respect to priority, no new matter has been presented. Therefore Applicants submit that a new oath/declaration is not necessary.

In response, the Examiner maintains that a new oath/declaration is required because the instant application presents claims for subject matter not originally claimed or embraced in the statement of the invention. The newly claimed subject matter is a kit comprising a catheter and a nucleic acid comprising a gene encoding p21. Applicants arguments with respect to incorporation by reference of the '470 patent and priority have not been found persuasive. See above. Accordingly, a new oath/declaration is required for the reasons of record. See page 3 of the Office action mailed on 9/12/02.

### ***Claim Rejections - 35 USC § 112, 1<sup>st</sup> paragraph***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 17-36 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The previous rejection is maintained for the reasons of record advanced on pages 6-8 of the Office action mailed on 9/12/02.

Applicant's arguments filed on 12/17/02 have been fully considered but are not found persuasive. Applicants have argued that as discussed with respect to the priority claim, the specification discloses a kit comprising a catheter and a nucleic acid encoding p21. Applicants submit that the written description requirements under 35 USC 112, 1<sup>st</sup> paragraph have been met and that no new matter has been presented.

In response, the Examiner maintains that the specification has not provided implicit or explicit support for the kit comprising a catheter and a nucleic acid encoding a p21 gene as embraced by the instant claims. The Examiner also maintains that the specification has not provided implicit or explicit support for a single balloon catheter embraced by the claims. Applicants are reminded that it is their burden to show where the specification supports any amendments to the claims. See pages 7-8 of the Office action mailed on 9/12/02 and also see 37 CFR 1.121 (b)(2)(iii), MPEP 714.02, 3<sup>rd</sup> paragraph and MPEP 2173.07. In light of such, it appears that the claim limitations directed to a kit and a single balloon catheter are new matter. Applicant's arguments with respect to priority were not found persuasive as discussed above.

Accordingly, the rejection is maintained for the reasons of record.

***Claim Rejections - 35 USC § 112, 2<sup>nd</sup> paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The previous rejections of claims 21 and 32-33 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention have been withdrawn in view of Applicant's amendments to the claims.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 17 and 19-36 are rejected under 35 U.S.C. 102(b) as being anticipated by Nabel et al (US 5,863,904). The previous rejection is maintained for the reasons of record advanced on pages 9-10 of the Office action mailed on 9/12/02.

Applicant's arguments filed on 12/17/02 have been fully considered but are not found persuasive. Applicants have argued that as discussed with respect to the priority claim, the instant application is entitled a filing date, which predates the publication date of the '409 patent.

In response, the Examiner maintains that Applicant's priority claim has been denied as discussed above. Therefore, the '904 patent qualifies as prior art under 35 USC 102(b). Accordingly, it is maintained that the '904 patent anticipates the instant claims. The previous rejection is maintained for the reasons of record.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

The previous double patenting rejections have been withdrawn in view of the terminal disclaimers filed over the '904, '372 and '300 patents.

### ***Terminal Disclaimers***

The terminal disclaimer filed on 12/17/02 disclaiming the terminal portion of any patent granted on this application, which would extend beyond the expiration date of 5,863,904, 6,057,300, and 6,218,372 has been reviewed and is accepted. The terminal disclaimer has been recorded.



***Conclusion***

**No claim is allowed.**

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Peter Paras, Jr., whose telephone number is 703-308-8340. The examiner can normally be reached Monday-Friday from 8:30 to 4:30 (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at 703-305-4051. Papers related to this application may be submitted by facsimile transmission. Papers should be faxed via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center numbers are (703) 308-4242 and (703) 305-3014.

Inquiries of a general nature or relating to the status of the application should be directed to Dianiece Jacobs whose telephone number is (703) 305-3388.

Peter Paras, Jr.

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A handwritten signature in black ink, appearing to read 'Michael Wilson', with a stylized, wavy flourish at the end.

**MICHAEL WILSON  
PRIMARY EXAMINER**